PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Adempas (riociguat)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Adempas is a soluble guanylate cyclase stimulator that is FDA approved for adults with persistent or recurrent Chronic Thromboembolic Pulmonary Hypertension (CTEPH) World Health Organization (WHO) Group 4 after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class. It is also approved for adults with PAH WHO Group 1 to improve exercise capacity, improve WHO functional class and to delay clinical worsening.

Adempas (riociguat) will be considered for coverage when the following criteria are met:

Pulmonary Arterial Hypertension [WHO Group 1]

For **initial** authorization:

1. Member is at least 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a cardiologist or pulmonologist; AND
3. Member must have a diagnosis of WHO Group 1 pulmonary arterial hypertension (PAH) confirmed by right heart catheterization; AND
4. Member has documentation of WHO functional class II, III or IV; AND
5. Member must have documentation of **ONE** of the following:
   a) Patient had an acute response to vasodilator testing AND has tried a calcium channel blocker (CCB) for at least 3 months;
   b) Patient did not have a response to vasodilator testing;
   c) Patient cannot undergo vasodilator testing;
   d) Patient cannot take CCB therapy; AND
6. Member has tried and failed a phosphodiesterase type 5 inhibitor (ie. sildenafil, tadalafil) AND endothelin receptor antagonist (ie. ambrisentan, bosentan, macitentan).
7. **Dosage allowed/Quantity limit:** Starting dose 1 mg three times per day. Increase dosage by 0.5 mg at intervals of no sooner than 2-weeks as tolerated to a maximum of 2.5 mg three times a day.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Member has documentation of improvement in signs and symptoms of disease as evidenced by at least **ONE** of the following:
   a) Stabilization or improvement in functional class symptoms;
   b) Stabilization or improvement in 6MWD (6-minute walk distance).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Chronic Thromboembolic Pulmonary Hypertension [WHO Group 4]

For **initial** authorization:
1. Member is at least 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a cardiologist or pulmonologist; AND
3. Member must have a diagnosis of WHO Group 4 CTEPH confirmed by right heart catheterization; AND
4. Member has documentation of WHO functional class II, III or IV; AND
5. Member has persistent or recurrent CTEPH after surgery (i.e. pulmonary endartectomy) OR is *not* a candidate for surgery.
6. **Dosage allowed/Quantity limit:** Starting dose 1 mg three times per day. Increase dosage by 0.5 mg at intervals of no sooner than 2-weeks as tolerated to a maximum of 2.5 mg three times a day.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Member has documentation of improvement in signs and symptoms of disease as evidenced by at least **ONE** of the following:
   a) Stabilization or improvement in functional class symptoms (see appendix);
   b) Stabilization or improvement in 6MWD (6-minute walk distance).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Adempas (riociguat) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
06/15/2011	Pulmonary Arterial Hypertension policy creation.
05/13/2014	Combined all PAH agents into one policy
07/09/2015	Revised guidelines for therapy aligning with CMS
08/18/2015	Revised guidelines to include diagnosis criteria
10/13/2021	Separated PAH agents by drug class; Updated guidelines; Added provider specialty; Included new FDA approval for CTEPH WHO Group 4
04/25/2023	Updated guidelines. Simplified reauthorization criteria for both diagnoses to align with package insert. Changed initial authorization to 6 months for all. Removed trial requirement of anticoagulant for CTEPH.
04/18/2024	Changed policy name from Soluble Guanylate Cyclase Stimulator for PAH to Adempas; added functional class requirement to PAH; added trial of ERA and PDE5i for WHO group 1 to PAH; removed PAH diagnosis from appendix.

Appendix:

World Health Organization Functional Assessment Classification	
Class I	Patients without resulting limitation of physical activity. Ordinary physical activity does not cause undue dyspnea, fatigue, chest pain or near syncope.
Class II	Patients with slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity increases dyspnea, fatigue, chest pain, or near syncope.

Class III	Patients with marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity increases dyspnea, fatigue, chest pain, or near syncope.
Class IV	Patients unable to carry out any physical activity without symptoms. These patients may have signs of right-heart failure. Dyspnea and/or fatigue may even by present at rest. Discomfort is increased by any physical activity.

References:

1. Adempas [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; 2023.
2. Coons, J.C., Pogue, K., Kolodziej, A.R. et al. Pulmonary Arterial Hypertension: a Pharmacotherapeutic Update. *Curr Cardiol Rep*. 2019; 21(141)
3. Klinger JR, Elliott CG, Levine DJ, et al. Therapy for Pulmonary Arterial Hypertension in Adults: Update of the CHEST Guideline and Expert Panel Report [published correction appears in Chest. 2021 Jan;159(1):457]. *Chest*. 2019;155(3):565-586. doi:10.1016/j.chest.2018.11.030
4. Benza RL, Ghofrani HA, Grünig E, Hoeper MM, Jansa P, Jing ZC, Kim NH, Langleben D, Simonneau G, Wang C, Busse D, Meier C, Ghio S. Effect of riociguat on right ventricular function in patients with pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension. *J Heart Lung Transplant.* 2021 Oct;40(10):1172-1180.
5. Humbert M, Kovacs G, Hoeper MM, et al. 2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension. *Eur Respir J*. 2023;61(1):2200879. Published 2023 Jan 6. doi:10.1183/13993003.00879-2022

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